REMARKS

Claims 1-2 are pending in the instant application. Claims 1-2 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §102

Claims 1-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mulligan-Kehoe et al. (2001) *J. Biol. Chem.* 276(11):8588-8596 (PTO 892). The Examiner suggests that Mulligan-Kehoe et al. teach a method for making a 34 kDa truncated plasmin proteolytic protein by combining rPAI-1_{23} encoded by nucleotides 444-999 of porcine rPAI-1_{23} or human rPAI-1_{23} encoded by nucleotides 238-293 and plasminogen for 1 hour at 37°C, then adding single chain urokinase plasminogen activator (uPA) for an additional 1 hour at 37°C so that a truncated plasmin proteolytic protein product is produced, the truncated plasmin proteolytic protein has a molecular weight of about 34 kDa. It is suggested that given that the method steps and reagents in the claimed method are allegedly the same as that of the reference as evidenced by the disclosure and the declaration of Mulligan-Kehoe filed on Dec. 22, 2005, the reference method inherently produces the same product, wherein the product is recognized by the same mini-plasminogen antibody. Applicant respectfully traverses this rejection.

Mulligan-Kehoe et al. teach the use of uPA (page 8589, column 2, fourth paragraph) with no teaching or suggestion of the nature of the uPA employed. Further, Mulligan-Kehoe et al. teach the production of a proteolytic cleavage product slightly greater

than the 34-kDa molecular mass marker (page 3591, last three lines of column 1 and the zymograph of Figure 5), which when more closely analyzed is actually ~36-38 kDa (see the sentence bridging columns 1 and 2 of page 8591). More specifically, Figure 5 (*e.g.*, lanes 10 and 11) discloses co-incubation of rPAI-1_{23}, plasminogen and "uPA" to produce the ~36-38 kDa protein band. When one looks to Figure 10, which allegedly shows the claimed method and product, the protein band near the 34 kDa molecular weight marker is approximately the same size in each lane independent of whether the reaction encompasses combining rPAI-1_{23} with plasminogen and subsequently adding "uPA" (see *e.g.*, lane 8 of Figure 10) or as shown in Figure 5 encompasses co-incubation of rPAI-1_{23}, plasminogen and "uPA" (see *e.g.*, lane 10 of Figure 10). As such, the proteolytic cleavage product disclosed throughout the teachings of Mulligan-Kehoe et al. is in fact a ~36-38 kDa protein with no teaching or suggestion of the production of a truncated plasmin proteolytic protein of 34 kDa which is recognized by a mini-plasminogen antibody. In this regard, the method steps and reagents disclosed by Mulligan-Kehoe et al. are not expressly or inherently the same as those of the present disclosure which involves combining plasminogen and rPAI-1_{23} for a specified amount of time and adding single chain uPA so that a 34 kDa truncated plasmin proteolytic protein which is recognized by a mini-plasminogen antibody is produced.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131.

Because the products of Mulligan-Kehoe et al. and the instant disclosure are of distinct sizes (~36-38 kDa vs. 34 kDa, respectively), the reagents in the methods used to produce these products must necessarily be distinct. Therefore, this reference cannot be held to expressly or inherently anticipate the present invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

II. Rejection of Claims Under 35 U.S.C. §112

Claims 1-2 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventor, at the time of filing of the application, had possession of the claimed invention. Specifically, the Examiner suggests that the "single chain urokinase plasminogen activator" in claim 1 is a departure from the specification and the claims as originally filed. It is suggested that page 64, line 8-20 discloses two-chain uPA is required for cleavage of plasminogen and two-chain uPA was used. Applicant respectfully traverses this rejection.

Applicant respectfully disagrees with the Examiner's suggestion that a single chain uPA departs from the specification and claims as filed. The general teachings of method for producing a 34 kDa truncated plasmin proteolytic protein (page 29) embrace combining plasminogen and rPAI-1_{23} for a specified amount of time and subsequently adding uPA to the reaction. The first paragraph at page 26 clearly teaches a comparison of two uPA proteins, namely single-chain uPA (scuPA) and two-chain uPA (tcuPA), in combination with rPAI-1_{23} and plasminogen, for

producing plasmin cleavage products, including two fragments between 34 kDa and 50 kDa produced by scuPA and fragments of slightly greater molecular mass produced by tcuPA. Accordingly, it is clear from the teachings of the disclosure at page 26 that in order to produce a plasmin cleavage product of 34 kDa, and not a slightly larger product, scuPA is employed as the uPA in the method disclosed at page 29. Accordingly, Applicant has reasonably conveyed the instant invention to one skilled in the art in accordance with the written description requirement. It is therefore respectfully requested that this rejection be withdrawn.

Respectfully submitted,

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